

REMARKS

Claims 2-28 and 48-60 stand rejected. Claims 2-28, 49-57, and 60 are currently pending in the subject application, of which claims 17, 18, 20, 27, 28, 49, 50, 51, 53-57, and 60 have been amended herein. Favorable reconsideration of the application is requested in view of the amendments and comments herein.

I. Objection to Claims 17 and 27 for Informalities

Claims 17 and 27 were objected to because of a missing word informality. It is respectfully submitted that claims 17 and 27 have been amended by adding the term "material" after the term "biocompatible" to remedy the objection. Withdrawal of the objection is respectfully requested.

II. Rejection of Claims 53-57 Under 35 U.S.C. §112 ¶2

Claims 53-57 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the application regards as the invention. Claims 53-57 have been amended to replace "cylindrical member" with the phrase "cylindrical enclosure" consistent with the terms utilized in independent claim 18. Accordingly, withdrawal of this rejection is respectfully requested.

III. Rejection of Claims 2, 17-21, 27, 28, 49, 51, 53, 54, 56, and 58-60 Under 35 U.S.C. §102(b)

Claims 2, 17-21, 27, 28, 49, 51, 53, 54, 56, and 58-60 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Pat. No. 5,855,601 to Bessler et al. ("Bessler et al."). Withdrawal of this rejection is respectfully requested for at least the following reasons.

Claim 18 has been amended to recite that the valve is a pulmonic valve. Since Bessler et al. fails to disclose the recited combination of claim 18 comprising a heart valve prosthesis that includes a pulmonic valve, Bessler et al. does not anticipate claim 18, nor does it anticipate dependent claims 2, 17, 19, 53, 54, and 56.

Additionally, claim 17 (which depends from claim 18) has been amended to recite that an outer sheath of a substantially biocompatible material covers the exposed parts of the support. In

contrast, Bessler et al. does not include an outer sheath that covers the exposed portions of the support. Instead, Bessler et al. discloses a cuff portion that is integral with the material that forms the valve. This cuff covers only a portion of the support, so as to leave much of the support exposed in contrast to claim 17. Accordingly, claim 17 is allowable over Bessler et al.

With respect to claims 53, 54, and 56, Bessler et al. fails to teach or suggest an implanter that includes a body portion from which a cylindrical enclosure extends, as recited in claim 53. Instead, Bessler et al. discloses a different type of implantation mechanism, namely a catheter, in which the valve is carried in a collapsed configuration. Since Bessler et al. does not teach the implanter of claim 53, claims 53, 54 and 56 are not anticipated by Bessler et al.

Claim 54 further has been amended to recite that the body portion of the implanter has a diameter that is greater than that of the cylindrical enclosure. Since Bessler et al. does not disclose such an implanter, claim 54 is not anticipated by Bessler et al.

Additionally, claim 56 has been amended to recite that the cylindrical enclosure and body portion of the implanter are substantially coaxial along a linear axis extending through the implanter (See, *e.g.*, Figure 19 of the instant application). In addition to Bessler et al. failing to disclose the body portion recited in amended claim 53, Bessler et al. also fails to disclose the coaxial relationship between the body portion and the cylindrical enclosure recited in claim 56. Therefore, claim 56 is not anticipated by Bessler et al.

Independent claim 20 has been amended to generally incorporate the subject matter of claim 48 such that the cylindrical member extends from a body portion and in which the body portion has a greater diameter than the cylindrical member. Since Bessler et al. fails to teach or suggest the combination recited in amended claim 20, claim 20 and claims depending therefrom (including but not limited to claims 21, 27, 28, 49, and 51) are not anticipated by Bessler et al.

Additionally, claim 27 has been amended to recite that an outer sheath of a substantially biocompatible material covers the exposed part of the support. In contrast, Bessler et al. does not include an outer sheath that covers the exposed portions of the support. Instead, Bessler et al. discloses a cuff portion integral with the material that forms the valve, which cuff covers only a portion of the support, leaving much of the support exposed. Accordingly, claim 27 is not anticipated by Bessler et al.

Additionally, dependent claim 28 has been amended to recite that the valve is a pulmonic animal heart valve having leaflets within a valve wall with the support engaging an outer surface of the valve wall. Bessler et al. does not teach a pulmonic animal heart valve, as recited in claim 28. Further, Bessler et al. fails to teach or suggest a pulmonic animal heart valve having leaflets within a valve wall that is engaged on an outer surface thereof by the support in which the valve is mounted. Instead, Bessler et al. teaches an artificial heart valve having leaflets extending from and integral with the bottom of the cuff that surrounds part of a support. The absence of a teaching or suggestion of the pulmonic valve and relationship between the pulmonic valve, valve wall, and support precludes anticipation of claim 28 by Bessler et al.

Claim 49 has also been amended to recite that the body portion has a diameter that is greater than that of the cylindrical member. Bessler et al. does not teach a body portion with a diameter greater than a cylindrical member. Thus, claim 49 is not anticipated by Bessler et al.

Additionally, claim 51 has been amended to recite that the cylindrical enclosure and body portion of the implanter are substantially coaxial along a linear axis extending through the implanter (See, *e.g.*, Figure 19 of the instant application). In addition to Bessler et al. failing to disclose the body portion recited in amended claim 20, as well Bessler's failure to disclose the relationship between the diameters of the cylindrical member and the body portion of claim 49, Bessler et al. also fails to disclose the coaxial relationship between the body portion and the cylindrical enclosure recited in claim 51. Therefore, claim 51 is not anticipated by Bessler et al.

Claims 58-59 have been cancelled and claim 60 has been rewritten to depend from amended claim 50. Since, claim 50 is allowable for the reasons noted herein, the rejection of claim 60 under 35 U.S.C. §102(b) in view of Bessler et al. is moot.

For the reasons stated herein, claims 2, 17-21, 27, 28, 51, 53, 54, 56, and 60 are patentable over Bessler et al. Accordingly, withdrawal of this rejection is respectfully requested.

IV. Rejection of Claims 3-16 and 22-26 Under 35 U.S.C. §103(a)

Claims 3-16 and 22-26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over US Pat. No. 5,855,601 to Bessler et al. in view of U.S. Pat. No. 6,077,296 to Shokoohi et al. ("Shokoohi et al."). Withdrawal of this rejection is respectfully requested for at least the following reasons.

Claims 3-16 depend from claim 2, which depends from claim 18. Claim 18 is allowable

over Bessler et al. due to Bessler's failure to teach or suggest the combination of claim 18 that includes a pulmonic heart valve. As mentioned above, Bessler et al. teaches an artificial heart valve having leaflets extending from and integral with a cuff that surrounds part of a support. The brief mention in Bessler et al. that the valve could be an aortic porcine valve demonstrates a failure of Bessler et al. to appreciate the benefits associated with employing a pulmonic valve in the recited combination of claim 18. Since Bessler et al., individually or in combination with Shokoohi et al. or any other cited art, neither teaches nor suggests the structural and functional interrelationships of claim 18, claim 18 is allowable. Further since claim 18 is allowable, claims depending from claim 18, including but not limited to claims 3-16, are also allowable.

The addition of Shokoohi et al. does not cure the deficiencies of Bessler et al. First, it is respectfully submitted that there is no proper motivation or suggestion to combine Shokoohi et al. with Bessler et al., as suggested in the Office Action. Specifically, Bessler et al. relates to implantation of an expandable artificial heart valve prosthesis, whereas Shokoohi et al. relates to an endoluminal vascular prosthesis that does not include a heart valve. It is submitted that there is no suggestion to use the wire support of Shokoohi et al. in combination with a heart valve as taught by Bessler et al. For example, such a proposition fails to appreciate the potential complexities associated with the combination of implanter and heart valve prosthesis recited in claim 18. Therefore, the rejection appears to be based on improper hindsight in which the instant application provides the missing teaching or motivation to combine Shokoohi et al. and Bessler et al. in the manner suggested in the Office Action.

Assuming *arguendo* that Shokoohi et al. is combined with Bessler et al., as suggested in the Office Action, it is respectfully submitted that the combination still fails to teach or suggest the subject matter recited in claims 3-16 and claims 22-26. As mentioned above, Bessler et al., alone or in combination with Shokoohi et al. or any other cited reference, still fails to teach or suggest the structural and functional interrelationships of claim 18 from which claims 13-16 depend. Shokoohi et al. further includes no teaching or suggestion that would enable one of ordinary skill in the art to mount a valve in the support taught by Shokoohi et al., as recited in claims 3-16 and 22-26.

Additionally, Claim 20 (from which claims 22-26 depend) was amended to recite an implanter that includes a body portion from which a cylindrical member extends to terminate in an opening spaced apart from the body portion. The body portion has a greater outer diameter

than the cylindrical member. Since neither Bessler et al., alone or in combination with Shokoohi et al. or any other cited reference(s), neither teaches nor suggests the structural and functional interrelationships of claim 20, claim 20 is patentable over the cited references. Accordingly, claims 22-26, which depend from claim 20 are also allowable.

For the reason stated above, claims 3-16 and 22-26 are patentable over the cited art and the rejection of said claims is respectfully requested to be withdrawn.

V. Rejection of Claims 50 and 55 Under 35 U.S.C. §103(a)

Claims 50 and 55 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bessler et al. in view of U.S. Pat. No. 6,540,782 to Snyders ("Snyders"). Withdrawal of this rejection is respectfully requested for at least the following reasons.

The addition of Snyders does not cure the deficiencies of Bessler et al. Claim 50 has been rewritten in independent form to substantially incorporate the subject matter of original claims 20 and 48 from which claim 50 depended. Minor clerical changes have also been made to facilitate readability of amended claim 50.

The Office Action relies on Snyders for its teaching of a handle corresponding to reference numbers 84 and 104 in the Snyders patent. Claim 50 recites a handle portion attached to a body portion at a position near a substantially opposite end of the body portion from which the cylindrical member extends. In contrast to the recitations of claims 50 and 55, however, the Snyders patent fails to disclose a handle that is attached to a body portion from which a cylindrical member extends and in which cylindrical member a heart valve prosthesis is mounted. Instead, the handle disclosed in the Snyders patent corresponds to a "handle" of an elongate tubular member that is connected to a manipulator for pushing the valve out of the holder. This is in sharp contrast to the handle that is attached to the body portion, as recited in claims 50 and 55. Accordingly, claims 50 and 55 are allowable over the suggested combination of Bessler et al. and Snyders patents.

For the reasons stated above, claims 50 and 55 are patentable over the cited art. Accordingly, withdrawal of this rejection is respectfully requested. Claim 60 has been amended to depend from claim 50 and to recite that the valve comprises a natural tissue pulmonic animal heart valve. Since Bessler et al., individually or in combination, fails to teach or suggest the implantation system of claim 60, claim 60 is allowable.

VI. Rejection of Claims 52 and 57 Under 35 U.S.C. §103(a)

Claims 52 and 57 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bessler et al. in view of U.S. Pat. No. 5,851,210 to Torossian ("Torossian"). Withdrawal of this rejection is respectfully requested for at least the following reasons.

The addition of the Torossian patent does not cure the deficiencies of Bessler et al. First, it is respectfully submitted that there is no proper motivation or suggestion to combine Torossian with Bessler et al., as suggested in the Office Action. Specifically, Bessler et al. relates to implantation of an expandable artificial heart valve prosthesis, whereas Torossian relates to a stent delivery system and method which does not involve implantation of a heart valve. It is submitted that there is no suggestion in the art to use the stent delivery system of Torossian in combination with implanting a heart valve. For example, such a proposition fails to appreciate the potential complexities associated with the combination of the implanter and heart valve prosthesis recited in claims 52 and 57. Therefore, the rejection appears to be based on improper hindsight in which the instant application provides the missing teaching or motivation to combine Torossian and Bessler et al. in the manner suggested in the Office Action.

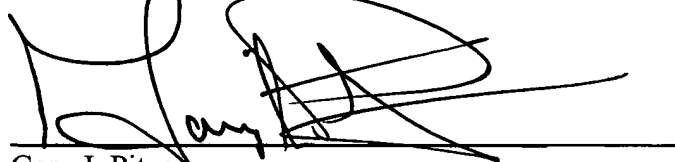
Assuming *arguendo* that Torossian is combined with Bessler et al., as suggested in the Office Action, it is respectfully submitted that the combination still fails to teach or suggest the subject matter recited in claims 52 and 57. In particular, since each of claims 18 and 20 is individually patentable over Bessler et al., alone as well as in combination with other art of record for the reasons stated herein above, claims 52 and 57 which depend respectively from claims 20 and 18 are also allowable (See, *e.g.*, sections III and IV *supra.*). Additionally, nothing in the Torossian patent or in Bessler et al. suggests or provides motivation to one of ordinary skill in the art to utilize the markers of Torossian on the type of implanter recited in claims 18 and 20. For this reason, an individual reasonably skilled in the art would not consider the subject matter recited in claims 52 and 57 obvious in light of prior art, namely the combination of Torossian and Bessler et al.

For the reason described above, claims 52 and 57 are patentable over the cited art. Accordingly, withdrawal of this rejection is respectfully requested.

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Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Gary J. Pitzer", is written over a horizontal line.

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